

## **FDA Issues Emergency Use Authorization for Over-the-Counter Injectable Drug for New World Screwworm in Dairy Cattle, Horses, Swine, Sheep, and Deer**

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The U.S. Food and Drug Administration today issued an Emergency Use Authorization (EUA) for Dectomax/Dectomax-CA1 (doramectin injection) injectable solution for the prevention and treatment of New World screwworm (NWS) infestations (myiasis) in dairy cattle (lactating dairy cows, dry dairy cows, and replacement dairy heifers 20 months of age and older), except for calves that will be processed for veal. The EUA also authorizes Dectomax/Dectomax-CA1 for the prevention of NWS myiasis in swine, horses at least one year old, sheep except for lactating sheep, and deer.

The FDA has concluded that based on the totality of the scientific evidence available, it is reasonable to believe that Dectomax/Dectomax-CA1 may be effective for the indications in the species described above, and the known and potential benefits of the product outweigh its known and potential risks.

Dectomax/Dectomax-CA1 is a single product with one label to reflect the product has:

- Approval (Dectomax) for the treatment and control of certain nematode and arthropod parasites in cattle and swine;
- Conditional approval (Dectomax-CA1) for NWS indications in beef cattle; and
- EUA (Dectomax/Dectomax-CA1) for NWS indications in dairy cattle, horses, swine, sheep, and deer.

### **Important Food Safety Information**

The FDA evaluated relevant human food safety information and concluded that the food products obtained from treated animals are safe for human consumption when the conditions of use granted by the EUA are followed, including the milk discard time and withdrawal periods. Adhering to the milk discard time and withdrawal periods helps avoid unsafe drug residues in animal-derived human foods.

#### *Milk Discard Time*

Milk taken from lactating dairy cows, dry dairy cows and replacement dairy heifers during treatment and for 468 hours (19.5 days) after treatment must not be used for human consumption.

### *Slaughter Withdrawal Periods*

Producers must wait the specified number of days after the last dose of Dectomax/Dectomax-CA1 before slaughtering treated animals for human consumption:

- Lactating dairy cows, dry dairy cows, replacement dairy heifers: 35 days
- Swine: 24 days
- Sheep: 35 days
- Deer: 35 days

### *Additional Limitations of Authorized Use*

- A withdrawal period has not been established for this product in pre-ruminating calves. Treated calves and calves born to treated cows must not be processed for veal.
- Do not use in horses less than one year old or horses intended for human consumption.
- Not authorized for use in lactating sheep. Use in these sheep may cause drug residues in their milk.

Detailed product information for this EUA can be found in the fact sheet about the [Dectomax/Dectomax-CA1 EUA for dairy cattle, swine, sheep, and deer](#); and the [fact sheet about the Dectomax/Dectomax-CA EUA for horses](#).

This EUA will be effective until it is revoked or the HHS Secretary terminates the [declaration](#) that the potential public health emergency presented by NWS justifies the emergency use authorization of animal drugs for NWS.

Dectomax/Dectomax-CA1 is sponsored by Zoetis Inc. of Parsippany, New Jersey.

### **Additional Information**

- [Freedom of Information Summary: Dectomax/Dectomax-CA1 \(EUA 006700\)](#)
- [Letter of Authorization: Dectomax/Dectomax-CA1 \(EUA 006700\)](#)
- [Fact Sheet: Emergency Use Authorization of Dectomax/Dectomax-CA1 \(doramectin injection\) for New World Screwworm \(NWS\): Dairy Cattle, Swine, Sheep, and Deer](#)
- [Fact Sheet: Emergency Use Authorization of Dectomax/Dectomax-CA1 \(doramectin injection\) for New World Screwworm \(NWS\): Horses](#)

- [Animal Drugs for New World Screwworm](#)
- [Emergency Use Authorization of Animal Drugs for NWS](#)